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May 20, 2004

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APPLICATION NUMBER: *60/459,475*
FILING DATE: *April 01, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/09971*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

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04-02

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J1064 U.S. PTO 04/01/03

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WEMMH SB/16 (4/03)

J1002 U.S. PTO 60/459475 04/01/03

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

Given Name (first and middle (if any))	Family Name or Surname	Residence (City and either State or Foreign Country)
Charles	Agnew	Lafayette, Indiana USA

☐ Additional inventors are being named on the ____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)

PERCUTANEOUSLY DEPLOYED VASCULAR VALVES WITH WALL-ADHERENT ADAPTATIONS

CORRESPONDENCE ADDRESS

Direct all correspondence to:

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OR Type Customer Number here

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ENCLOSED APPLICATION PARTS (check all that apply)

☒	Specification	Number of Pages: 19	☐	CD(s), Number	
☒	Drawing(s)	Number of Sheets: 5	☐	Other	
☐	Application Data Sheet. See 37 CFR 1.76				

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check all that apply)

		Filing Fee Amount($)
☐	Applicant claims small entity status. See 37 CFR 1.27.	
☒	A check or money order is enclosed to cover the filing fees	
☒	The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 23-3030	$160.00
☐	Payment by credit card. Form PTO-2038 is attached.	

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: .....

.....

Respectfully Submitted,

SIGNATURE Matthew R. Schantz

Date April 1, 2003

TYPED or PRINTED NAME Matthew R. Schantz

REGISTRATION NO. (if appropriate) 40,800

Docket Number: 3006-1415

TELEPHONE (317) 634-3456

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 003006-001415.KAG.213472/am

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Amy Miske

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60459475.040103

003006-001415.KAG.213474/am WEMMH/SB/17 (4/03)

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FEE TRANSMITTAL FOR FY 2003

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Total Amount of Payment	($)160.00

Complete if Known	
Application Number	Application filed herewith
Filing Date	April 1, 2003
First Named Inventor	Agnew, Charles
Group Art Unit	
Examiner Name	
Attorney Docket Number	3006-1415

METHOD OF PAYMENT

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

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Deposit Account Number: 23-3030

Deposit Account Name: Woodard, Emhardt, Moriarty, McNett & Henry LLP

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FEE CALCULATION

1. BASIC FILING FEE

Large Fee Code	Entity Fee ($)	Small Fee Code	Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility Filing Fee	
1002	330	2002	165	Design Filing Fee	
1003	520	2003	260	Plant Filing Fee	
1004	750	2004	375	Reissue Filing Fee	
1005	160	2005	80	Provisional Filing Fee	160.00
				SUBTOTAL (1)	($) 160.00

2. EXTRA CLAIM FEES

		Extra Claims	Fee From Below	Fee Paid
Total Claims	-20** =		X =	
Independent Claims	-3** =		X =	
Multiple Dependent			=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
	18		9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

***or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge – late filing fee or oath	
1052	50	2052	25	Surcharge – late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner's Action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner's Action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,300	2453	650	Petition to revive – unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Petitions related to provisional applications	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other Fee (specify) .....

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)

SUBMITTED BY

Complete (if applicable)

Name (Print/Type)	Matthew R. Schantz	Registration No. (Attorney/Agent)	40,800	Telephone	(317) 634-3456
Signature	Matthew R. Schantz			Date	April 1, 2003

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003006-001415.KAG.213555/AM

PERCUTANEOUSLY DEPLOYED VASCULAR VALVES WITH WALL-ADHERENT ADAPTATIONS

BACKGROUND AND SUMMARY OF THE INVENTION

[0001] The present invention relates generally to medical devices and in particular to artificial vascular valve devices.

[0002] In one embodiment, the present invention provides a vascular valve that comprises a stentless vascular valve body having at least one flexible member for restricting blood flow. The flexible member has an edge for engaging a wall of a vascular vessel. The valve also includes wall-engaging adaptations located along the edge. The wall-engaging adaptations can include any suitable devices or materials such as barbs, adhesives, or the like. In preferred devices, the stentless vascular valve body is made with a remodelable material and in particular a remodelable extracellular matrix material.

[0003] In another embodiment, the invention provides a percutaneous vascular valve and delivery system. This system includes a stentless vascular valve body having at least one flexible member for restricting blood flow, the flexible member having an edge for engaging a wall of a vascular vessel. This system further includes a

percutaneous deployment device, wherein the deployment device has an expandable element adapted to force the edge against the vessel wall. Suitable stentless vascular valve bodies are as described above. Suitable percutaneous deployment devices may include a balloon catheter having adaptations for selectively forcing the edge against the vessel wall, or and elongate devices having at least one expandable frame attached thereto with adaptations for expanding and contracting the frame while remaining attached to the elongate device. The stentless valve body may be releasably attached to the deployment device by any suitable means including by the use of adhesives or removable elements such as removable sutures.

[0004] The invention also provides a method for treating venous insufficiency, wherein the method includes deploying a stentless vascular valve body such as that described above so as to force and selectively attach edges of the valve body against the vascular wall, to seat the valve within the vein.

[0005] Additional embodiments as well as features and advantages of the invention will be apparent to those skilled in the art from the descriptions herein.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0006] For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, and alterations and modifications in the illustrated device, and further applications of the principles of the invention as illustrated therein are herein contemplated as would normally occur to one skilled in the art to which the invention relates.

[0007] As disclosed above, the present invention provides vascular valve devices, and systems and methods for the delivery thereof. With reference now to Figure 1, shown is a perspective view of an illustrative valve device 11 of the present invention. Device 11 includes a stentless valve body formed of a flexible material 12, wherein in the illustrated embodiment the valve body includes a first leaflet 13 and a second leaflet 14. It will be understood in this regard that valve bodies having one leaflet, or a plurality of leaflets, e.g. two, three, four, five or more leaflets, are contemplated as within the scope of the present invention.

[0008] The valve body of device 11 includes an opening 15, configured to facilitate the valve function by selectively allowing blood flow in a first direction, and selectively restricting blood flow in a second direction opposite the first direction. Device 11 in particular is designed to facilitate net blood flow in the direction of the arrow. Leaflets 13 and 14 are formed with a flexible material and move outwardly to open the opening 15 when subjected to blood flow in the direction of the arrow, and move inwardly to close the opening 15 when subjected to blood flow in a direction opposite that of the arrow.

[0009] Device 11 also includes a lip 16 or other reinforcement along the edges of the leaflets 13 and 14. This lip 16 may be made from the same material or a different material than that of the leaflets 13 and 14. For example, lip 16 may be made by folding, rolling, or otherwise gathering and securing material at the periphery of material from which leaflets 13 and 14 are made. Alternatively, a different material may be secured to the periphery of leaflets 13 and 14 to provide the lip or other reinforcement. Still further, leaflets 13 and 14 may be integrally made with a reinforced lip 16, for example by molding, and/or material at the periphery of leaflets 13 and 14 may be treated to increase its strength relative to

the remainder of leaflets 13 and 14, for example by adding crosslinking to the periphery where leaflets 13 and 14 are made of collagenous materials.

[0010] Lip 16 incorporates adaptations for attachment to the vessel wall. For example, lip 16 can include a plurality of elements configured to partially or completely penetrate the vessel walls, for example barbs or hooks. Alternatively or in addition, lip 16 can be provided with a biocompatible adhesive sufficient to secure lip 16 to the vessel wall. A range of biocompatible adhesives are known and can be used in the present invention for this purpose.

[0011] With reference now to Figures 1A-1C, shown are a number of ways to incorporate barbs into the lip 16 of the device 11. In Figure 1A, barbs 17 are provided with a suturable base, and each base is secured with individual suture knots 19 within a fold created along stitch line 18. In Figure 1B, barbs 17 are provided along a wire element 20, with each barb 17 having a base 21 spaced from the others along the wire element 20. This wire element can similarly be stitched underneath a fold at the edge of leaflets 13 and 14, with the barbs penetrating the material at the edge of the leaflets 13 and 14. It will be understood that in this disclosed embodiment, this wire element does not constitute a stent, as it does not serve

to itself exert radial force upon the vessel walls to retain the position of the device, as would a stent. To the contrary, in certain embodiments, wire element 20 can be highly maleable, taking on the configuration to which it is forced, while not having sufficient resiliency or integrity to maintain significant radial force against a vessel wall. In Figure 1C, each barb 17 has a base 22 that is individually bonded to the periphery of the leaflets 13 and 14, for example with a suitable biocompatible adhesive. Still other means for securing barbs or similar attachment elements to the device 11 will be apparent to those skilled in the art given the teachings herein.

[0012] Referring now to Figure 2, shown is another embodiment of valve device 11, which is similar to that shown in Figure 1 except in respect of the attachment elements along the periphery of the leaflets. In particular, Figure 2 shows device 11 having a multitude of small, closely spaced vessel-wall-penetrating hooks 24 along the periphery of the valve body. To facilitate attachment, the small hooks are provided in a regular or irregular array along the lip of the device, particularly wherein the array includes hooks occurring generally longitudinally and laterally with respect to one another. That is, the array or swath of hooks along the periphery is

desirably two or more hooks wide, and as well extends longitudinally along the periphery.

[0013] Figure 3 provides a perspective view of one illustrative percutaneous deployment device of the invention. Deployment device 31 generally includes an expandable frame 32 attached to an elongate member 34 such as a stylet, received within a lumenal device such as a catheter 33. Distal tip 35 of elongate member 34 is designed to be non-damaging to vessels in which it is to be deployed. A first end of frame 32 is connected at or near distal tip 35 by struts 36, and a second end of frame 32 is connected to member 34 at a more proximal location by struts 37. Frame 32 is shown in its expanded configuration, deployed by pushing the end of stylet 34 out of the end of catheter 33. Frame 32 of device 31 has wire or other frame elements configured to selectively force lip 16 against the vessel wall in a path extending longitudinally along and at least partially circumferentially around the vessel wall, e.g. in a generally serpentine pattern. Frame 32 can be retracted back into catheter 33 by pulling stylet 34 proximally, thus collapsing struts 37, frame 32 and struts 36 for receipt within catheter 33. The end opening of catheter 33 may be configured with a taper or other adaptation to facilitate

collapse and receipt of these frame and strut elements, if desired. Additionally, in an alternate embodiment, proximal struts 37 can be attached to catheter 33, rather than stylet 34. In this fashion, frame 32 may reside externally of catheter 33 during the entire delivery and deployment operation. In this latter embodiment, where frame 32 is self-expanding, forcing the stylet 34 distally outward from the catheter will retain a collapsed frame configuration, and removing that force will allow frame 32 expansion. Where frame 32 is not self-expanding, it may be caused to expand by pulling stylet 34 proximally, and caused or allowed to regain a collapsed configuration by causing or allowing the stylet 34 to move distally.

[0014] With reference now to Figures 1-4 together, shown in Figure 4 is a vascular valve deployment system 41 having a stentless valve body 11 (FIG. 1 or 2) received upon deployment system 31 as shown in Figure 3. In the illustrated system 41, valve body 11 is releasably attached to the frame 32 by a suture 38 wound through body 11 and around frame 32. Suture 38 extends into and through the lumen of catheter 32, such that a physician can pull and remove the suture 38 after deployment of the valve body 11 against the vessel wall. In this regard, other means for releasably retaining valve body 11 on frame 32 may also be

used, including for example the use of tacky materials such as biocompatible polymers, e.g. a polyvinylpyrrolidone polymer. Suitable polyvinylpyrrolidone polymers that provide tack are known and commercially available, and can be used in the present invention. Other biocompatible adhesives are also known and can be used to secure lip 16 to frame 32.

[0015] Referring now to Figure 5, shown is another vascular valve deployment system 51 of the invention. System 51 includes a delivery device 52 including an outer sheath 53 and a delivery catheter 54 receivable therein. Delivery catheter 54 includes a relatively narrow section 55 underlying an inflatable balloon 57, to facilitate receipt of the balloon 57, when deflated, into the outer sheath 53. Delivery catheter 54 also includes a distal tip 56 adapted to be non-damaging to the vascular vessel in which it is used.

[0016] Balloon 57 includes adaptations that allow it to selectively force the lip 16 or edge of valve body 11 (see e.g. Figures 1 and 2) against the vessel wall. In the illustrated embodiment 51, balloon 57 adopts a predetermined shape upon inflation, the shape including at least one edge 58 configured to follow the lip 16 or other edge of valve body 11. A balloon that is partially or

wholly non-compliant (e.g. having sufficient rigidity or stiffness, altogether or in appropriate areas, to inflate to the predetermined, regular shape) may be used for these purposes. In this manner, when balloon 57 is inflated, balloon edge 58 will force lip 16 against the vessel wall to secure the lip 16 to the vessel wall. As discussed hereinabove, barbs may be used to facilitate this attachment. In the illustrated system 51, a biocompatible adhesive 51 is incorporated along lip 16 for these purposes.

[0017] The flexible material (e.g., 12, Figure 1) used in valve bodies of the invention is a biocompatible material, and is preferably a remodelable material. Suitable remodelable materials may be made from natural or synthetic polymers, and preferred materials comprise collagen. Thus, in general, the flexible material may comprise a material such as synthetic biocompatible polymers such as cellulose acetate, cellulose nitrate, silicone, polyethylene teraphthalate, polyurethane, polyamide, polyester, polyorthoester, polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular weight polyethylene, polytetrafluoroethylene, or mixtures or copolymers thereof; polylactic acid, polyglycolic acid or copolymers thereof, a polyanhydride, polycaprolactone,

polyhydroxy-butyrate valerate, polyhydroxyalkanoate, or another biodegradable polymer.

[0018] In certain embodiments of the invention, the flexible material 12 is comprised of a naturally derived or synthetic collagenous material, and especially an extracellular matrix material. Suitable extracellular matrix materials include, for instance, submucosa (including for example small intestinal submucosa, stomach submucosa, urinary bladder submucosa, or uterine submucosa), renal capsule membrane, dura mater, pericardium, serosa, peritoneum or basement membrane materials, including liver basement membrane. These layers may be isolated and used as intact natural sheet forms, or reconstituted collagen layers including collagen derived from these materials or other collagenous materials may be used. For additional information as to submucosa materials useful in the present invention, and their isolation and treatment, reference can be made to U.S. Patent Nos. 4,902,508, 5,554,389, 5,993,844, 6,206,931, and 6,099,567. Renal capsule tissue can also be obtained from warm blooded vertebrates, as described more particularly in copending United States patent application serial No. 10/186,150 filed June 28, 2002 and International Patent Application

serial No. PCT/US02/20499 filed June 28, 2002, published January 9, 2003 as WO03002165.

[0019] Frame elements 32, struts 36, 37, stylets 34, barbs 17, hooks 24, and other components of the present invention may also be made with any suitable biocompatible material. These include for example metals such as nitinol or other shape-memory materials, or stainless steel, as well as resorbable or nonresorbable polymeric materials, including those discussed above.

[0020] Devices and systems of the invention are desirably adapted for deployment within the vascular system, and in particularly preferred embodiments, devices and systems of the invention are adapted for deployment within the venous system. Accordingly, preferred devices such as device 11 are adapted as venous valves, for example for percutaneous implantation within veins of the legs or feet, to treat venous insufficiency.

[0021] It will be understood that other valve body configurations are contemplated as being within the scope of the present invention. For example, valves disclosed in published U.S. Patent Application Serial No. 777,091 filed February 5, 2001, published as 20010039450 on November 8, 2001, can be modified to provide valve devices and systems in accordance with the present invention (including the

removal of any stent or frame elements present in the prior-disclosed valves).

[0022] While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected. In addition, all publications cited herein are indicative of the abilities of those of ordinary skill in the art and are hereby incorporated by reference in their entirety as if individually incorporated by reference and fully set forth.

WHAT IS CLAIMED IS:

1. A percutaneous vascular valve, comprising:

a stentless vascular valve body having at least one flexible member for restricting blood flow, the flexible member having an edge for contacting a wall of a vascular vessel;

said edge adapted to attach to said wall.

2. The valve of claim 1, wherein said edge includes barbs.

3. The valve of claim 1 or 2, wherein said edge includes an adhesive.

4. The valve of any of claims 1-3, wherein said flexible member comprises a remodelable material.

5. The valve of any of claims 1-4, wherein said flexible member comprises a collagenous material.

6. The valve of claim 5, wherein said collagenous material comprises an extracellular matrix.

7. The valve of claim 6, wherein the extracellular matrix comprises submucosa.

8. The valve of any of claims 1-7, wherein the stentless vascular valve body comprises at least two leaflets.

9. The valve of any of claims 1-8, wherein said edge is configured to extend longitudinally along and at least partially circumferentially around the vessel wall.

10. The valve of any of claims 1-9, wherein said edge is a reinforced edge.

11. The valve of claim 10, wherein said reinforced edge has a thickness greater than a central portion of said flexible member.

12. A percutaneous vascular valve and delivery system, comprising:

a stentless vascular valve body having at least one flexible member for restricting blood flow, the flexible member having an edge for attachment to a wall of a vascular vessel;

a percutaneous deployment device, the deployment device having an expandable element for selectively forcing said edge against the wall.

13. The valve and delivery system of claim 12, wherein said edge has a plurality of mechanical elements for attaching to said wall.

14. The valve and delivery system of claim 13, wherein said mechanical elements include barbs.

15. The valve and delivery system of any of claims 12-14, wherein said edge includes an adhesive.

16. The valve and delivery system of any of claims 12-15, wherein said expandable element comprises a wire frame.

17. The valve and delivery system of any of claims 12-16, wherein said stentless valve body comprises a remodelable material.

18. The valve and delivery system of claim 17, wherein said remodelable material is collagenous.

19. The valve and delivery system of any of claims 12-18, wherein the stentless valve body is releasably attached to the expandable element.

20. The valve and delivery system of claim 19, wherein the stentless valve body is releasably attached to the expandable element with an adhesive.

21. The valve and delivery system of claim 19, wherein the stentless valve body is releasably attached to the expandable element with a removable component.

22. The valve and delivery system of claim 21, wherein the removable component comprises a removable suture.

23. The valve and delivery system of claim 19, wherein the stentless valve body is releasably attached to the expandable element by an attachment adaptation on said body, said element, or both.

24. A medical device, comprising a valve of any of claims 1-11, in combination with a percutaneous deployment device.

25. The medical device of claim 19, wherein said percutaneous deployment device has at least one expandable element for forcing said edge of said valve against a vessel wall.

ABSTRACT OF THE DISCLOSURE

[0023] Described are stentless, percutaneous vascular valves and deployment systems for providing selective attachment of the valves within a vascular vessel.

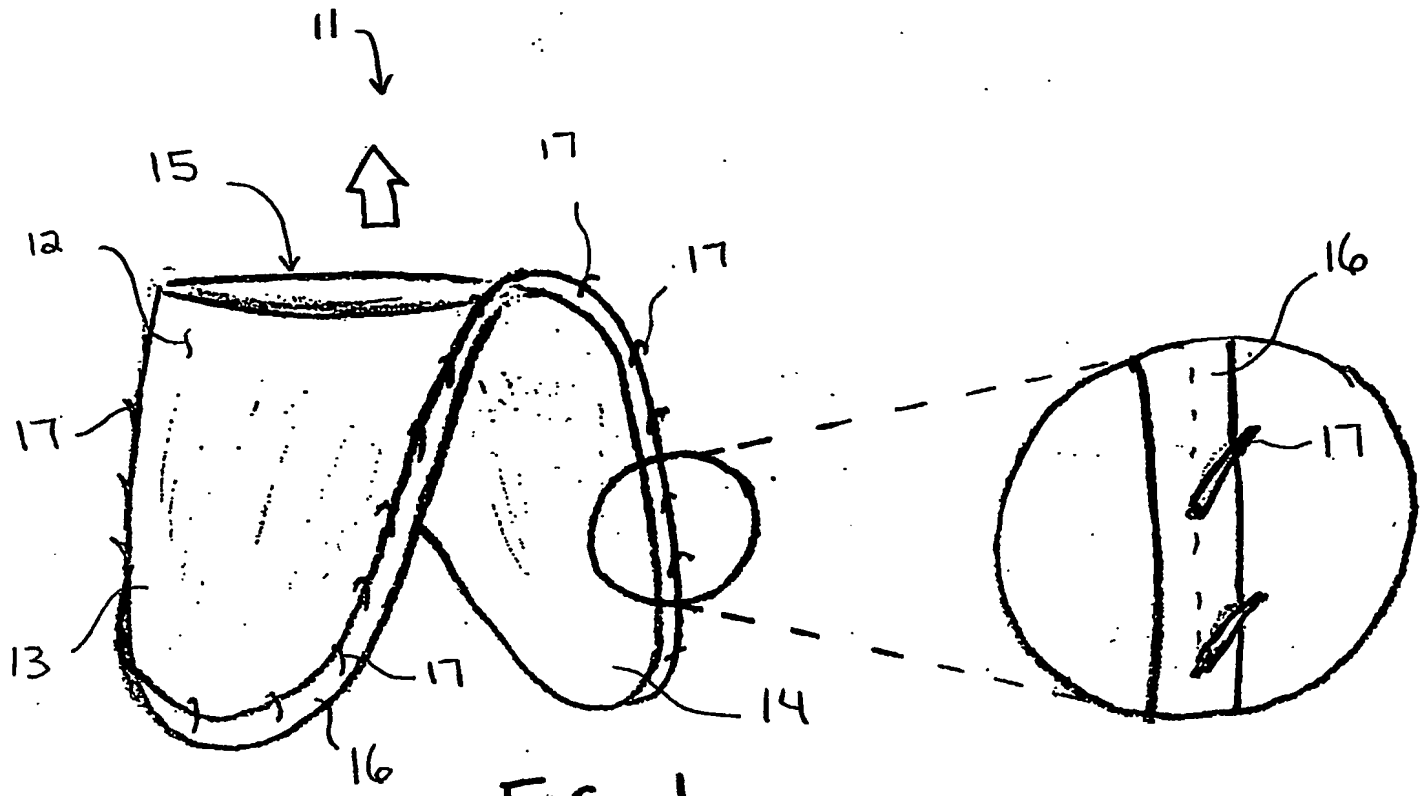

FIG. 1

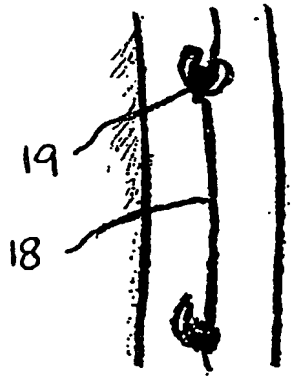

FIG. 1A

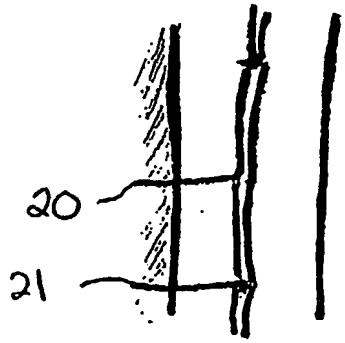

FIG. 1B

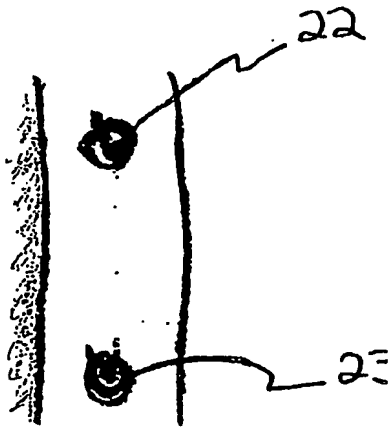

FIG. 1C

FIG. 2

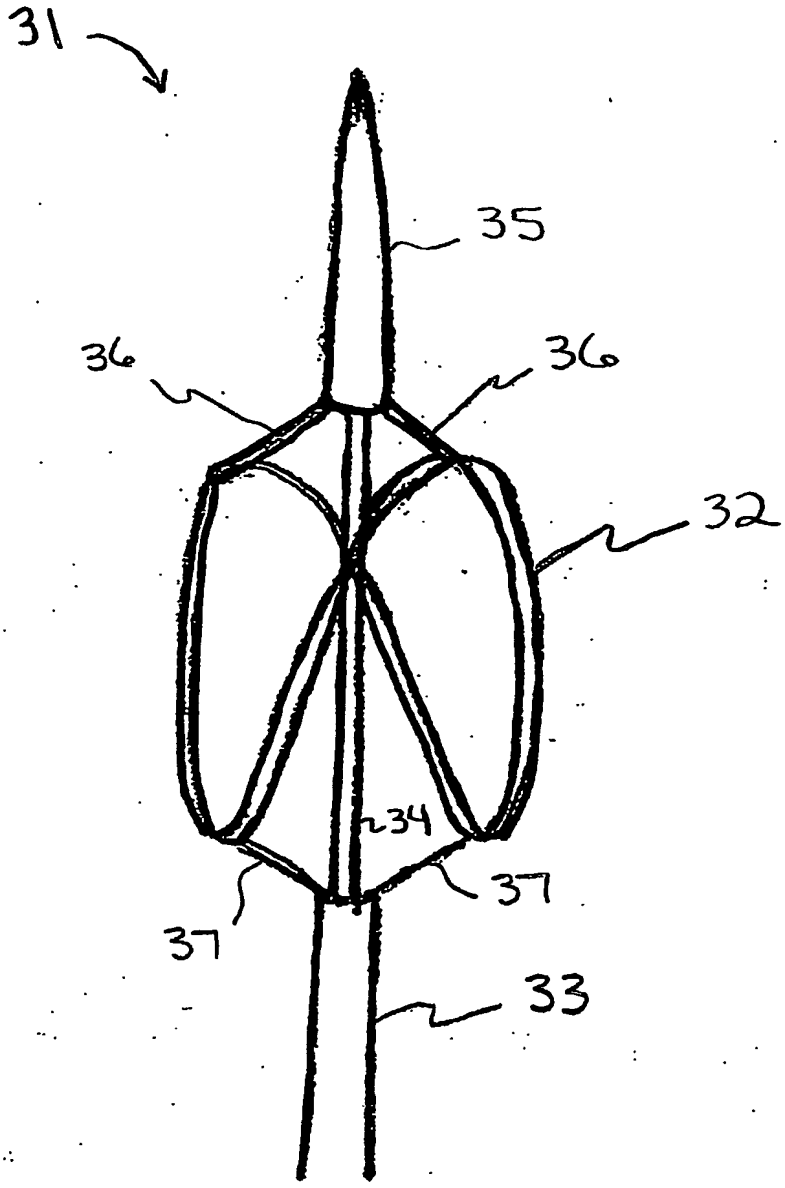

FIG. 3

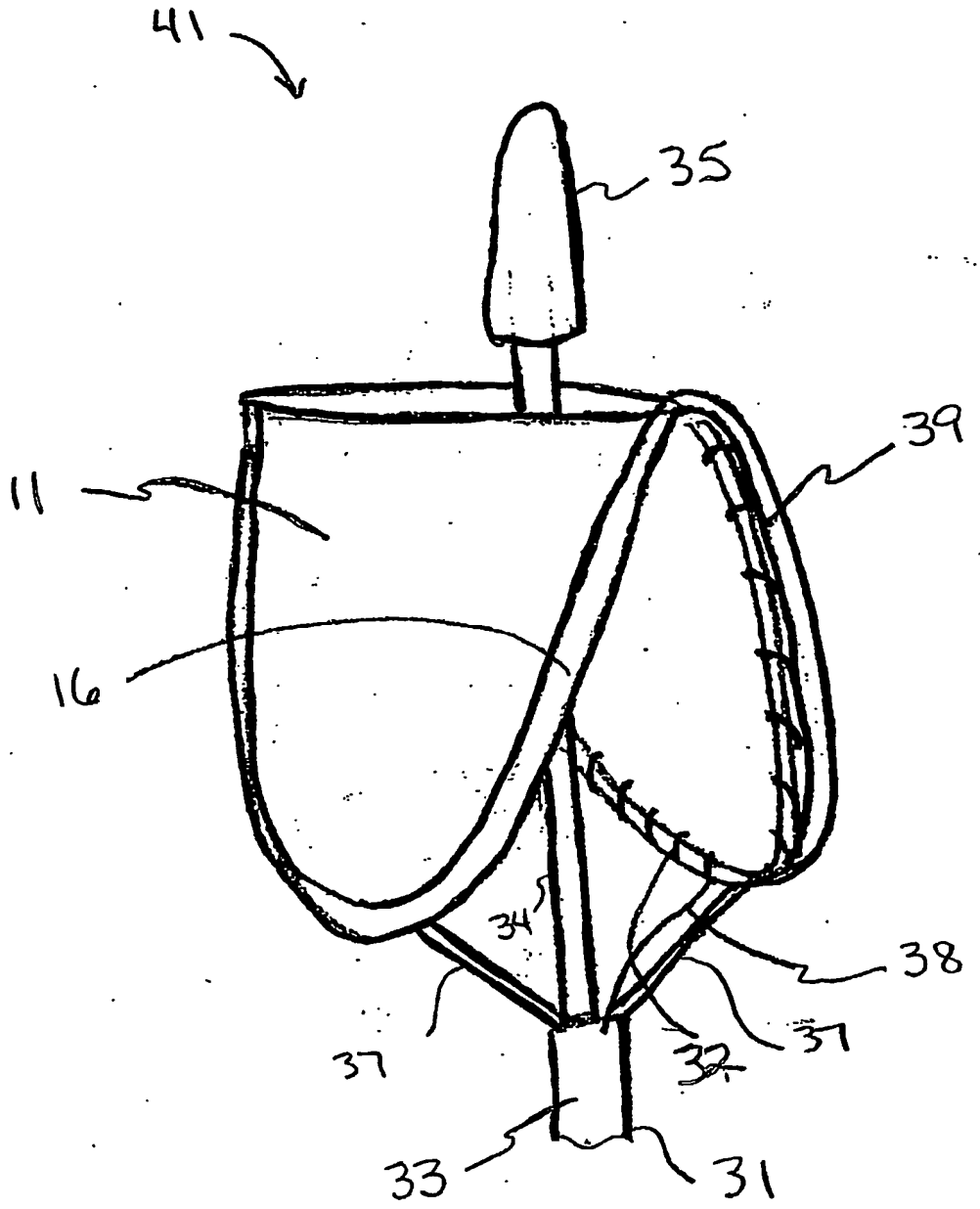

FIG. 4

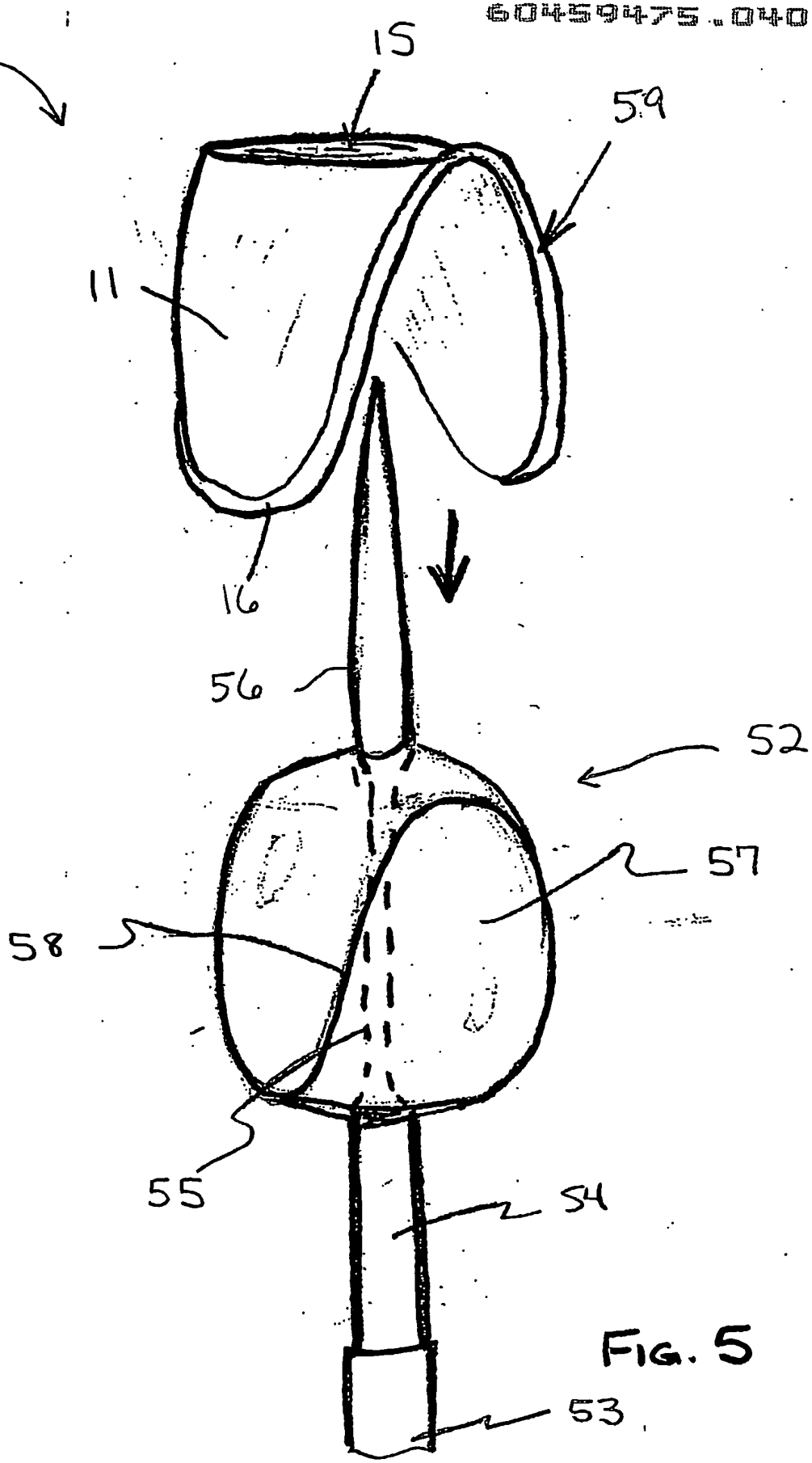

FIG. 5